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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/623,793	09/08/2000	Wesley H Verkaart	70869-0068US	6666

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EXAMINER

SIEFKE, SAMUEL P

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 08/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/623,793

Applicant(s)

VERKAART ET AL.

Examiner

Samuel P. Siefke

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-10 and 15-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-10 and 15-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/23/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims **1,3-10** and **14-19** are rejected under 35 U.S.C. 102(e) as being anticipated by Esposito (USPN 5,997,811).

Esposito discloses a syringe and a syringe package sterile apparatus that comprises: a syringe for transferring non-sterile; a casing first part (50) and a second part (30; col. 4, lines 1-50) configured to receive a sterile syringe (20) containing a non-sterile fluid (col. 2, lines 4-9). The non-sterile fluid flows through the first part (50) and into the sterile syringe, which is in the sterile package. The first part (50, lap joint or luer connector, col. 2, lines 13-29) receives the barrel portion of the syringe and the second part (30) receives the plunger portion of syringe (see fig. 1). The first part (50) is a rigid tube and the second part (30) is flexible sheet (sheath, shape of a bag)(see fig. 1; col. 4, lines 1-12). The second part (30) creates a bellows when the user applies pressure to the plunger to draw fluid into the syringe. The sterile sheath of the sterile syringe package can be made of a radiation stable thermoplastic material or a breathable

Art Unit: 1743

material sterilizable by gas or steam (col. 2, lines 24-28). It is noted that Esposito discloses the sheath may be made from a flexible material such as a thermoplastic material (col. 5, line 6, fig. 2, shows flexibility).

Response to Arguments

Applicant's arguments filed 6/6/05 have been fully considered but they are not persuasive. Applicant argues, "The Examiner is requested to reconsider the rejection in light of the discussion regarding functional limitations in the MPEP at section 2173.05(g)." Esposito discloses in a preferred embodiment of the present invention, a fluid can be introduced into the sterile syringe 20 encased in the syringe packaging 10. Since the encased syringe 20 does not have a needle thereon for the above reasons, another syringe or other fluid source (not shown) can be employed to inject the fluid into the encased syringe 20 through the fitting member 50 of the syringe packaging 10 and the luer or needle fitting 22 of the syringe 20. Then, the syringe package 1 may be subjected to subsequent processing including transportation (col. 5, lines 37-47). Further claim 1 of Esposito discloses: sterilizing a syringe package, which package is adapted to receive and encase the syringe in a sterile manner **while permitting operation of the syringe**. This statement and the above paragraph specifically state that the syringe can be operated within the sterile enclosure, which enclosure is made

Art Unit: 1743

from a flexible material such as a thermoplastic material (col. 5, line 6, fig. 2, shows flexibility).

Applicant argues, "It is respectfully submitted that the functional recitations in the instant claims are definite under 35 USC 112, second paragraph." The Examiner agrees with statement. The limitations were considered above and the prior art meets all of the limitations of the instant application.

Applicant argues, "It is again pointed out that Esposito does not show a two-part enclosure where a first part receives the barrel, the second part receives the plunger, and sterility is maintained when the first and second parts are connected. Thus, Esposito does not anticipate the claims, and the rejection under 35 USC 9102 cannot stand." Esposito discloses a syringe and a syringe package sterile apparatus that comprises: a syringe 20 for transferring non-sterile; a casing first part (50) and a second part (30; col. 4, lines 1-50) configured to receive a sterile syringe (20) containing a non-sterile fluid (col. 2, lines 4-9). The non-sterile fluid flows through the first part (50) and into the sterile syringe, which is in the sterile package. The first part (50, lap joint or luer connector, col. 2, lines 13-29) receives the barrel portion of the syringe and the second part (30) receives the plunger portion of syringe (see fig. 1).

With respect to the first part being readily detachable from the second part. Esposito discloses that the sterile sheath 30 can have a tear off portion 42 where the sheath can be torn open or peeled open by the user to deliver the sterile syringe 20 to the a sterile environment. The tear off portion 42 overlaps at least a portion of the sealing line 40. When being peeled open, the sealing line 40 breaks so that the first

Art Unit: 1743

and second sheets 38a and 38b can depart from each other therealong. Therefore the first part 50 is readily detachable from 38a and 38b because when the sheath is opened the first part 50 is still attached to the syringe.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

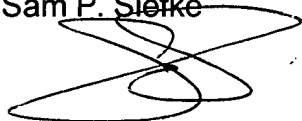
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel P. Siefke whose telephone number is 571-272-1262. The examiner can normally be reached on M-F 7:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1700. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.


Art Unit: 1743

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sam P. Siefke



August 18, 2005



Jill Warden
Supervisory Patent Examiner
Technology Center 1700